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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/537,102	KUJA-PANULA ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 10,2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, 8, 20 (in part), 58 (in part), drawn to an isolated AMIGO nucleic acid and a pharmaceutical composition comprising the nucleic acid.

Group II, claim(s) 7, 20 (in part), 58 (in part), drawn to an isolated AMIGO polypeptide and a pharmaceutical composition comprising the polypeptide.

Group III, claim(s) 9 and 10, drawn to a method of producing antibodies against an AMIGO polypeptide.

Group IV, claim(s) 11, 12, 13 (in part), 15 and 20 (in part), drawn to an antibody against an AMIGO polypeptide, a kit containing the antibody and a pharmaceutical composition comprising the antibody.

Group V, claim(s) 13 (in part), 14, 16, 17, drawn to a kit containing the reagents that can detect the presence of AMIGO or allelic variant comprising primers/probes.

Group VI, claim(s) 18, 19, drawn to a non-human transgenic animal of AMIGO.

Group VII, claim(s) 21, drawn to a method for treating a condition dependent on AMIGO.

Group VIII, claim(s) 22, drawn to a method for affinity purification of ligand that binds to AMIGO.

Group IX, claim(s) 23, 26-36, drawn to a method for identifying a modulator of binding between AMIGO receptors.

Group X, claim(s) 24, drawn to a method for making the modulator as identified from Group IX.

Group XI, claim(s) 25, drawn to a method of testing the modulator as identified from Group IX in vivo.

Group XII, claim(s) 37, drawn to a method for screening for a selectivity of a modulator of binding between an AMIGO and an EGFR.

Group XIII, claim(s) 38-47 (all in part), drawn to a method of modulating growth, migration, axonal growth, myelination, fasciculation of neuronal cells/ cancer/metastasis in a mammalian organism.

Group XIV, claim(s) 38-47 (all in part), 48-57, drawn to a method of modulating growth, migration, proliferation of cells/ cancer/metastasis in a mammalian organism.

Group XV, claim(s) 59-61, drawn to a method of modulating the phosphorylation of a human EGFR in cells/tissues.

2. The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is drawn to a technical feature of an isolated AMIGO nucleic acid and a pharmaceutical composition comprising the nucleic acid. The 1st claimed invention does not have a single inventive concept because the invention encompasses different

nucleic acid sequences, which does not share a common special corresponding technical feature as they comprise different compositions and structural features. In addition, Group II is drawn to a technical feature of an isolated AMIGO polypeptide and a pharmaceutical composition comprising the polypeptide.

Group III is drawn to a technical feature of a method of producing antibodies against an AMIGO polypeptide.

Group IV is drawn to a technical feature of an antibody against an AMIGO polypeptide, a kit containing the antibody and a pharmaceutical composition comprising the antibody.

Group V is drawn to a technical feature of a kit containing the reagents that can detect the presence of AMIGO or allelic variant comprising primers/probes.

Group VI is drawn to a technical feature of a non-human transgenic animal of an AMIGO.

Group VII is drawn to a technical feature of a method for treating a condition dependent on AMIGO.

Group VIII is drawn to a technical feature of a method for affinity purification of ligand that binds to AMIGO.

Group IX is drawn to a technical feature of a method for identifying a modulator of binding between AMIGO receptors.

Group X is drawn to a technical feature of a method for making the modulator as identified from Group IX.

Group XI is drawn to a technical feature of a method of testing the modulator as identified from Group IX in vivo.

Group XII is drawn to a technical feature of a method for screening for a selectivity of a modulator of binding between an AMIGO and an EGFR.

Group XIII is drawn to a technical feature of a method of modulating growth, migration, axonal growth, myelination, fasciculation of neuronal cells in a mammalian organism.

Group XIV is drawn to a technical feature of a method of modulating growth, migration, proliferation of cells/ cancer/metastasis in a mammalian organism.

Group XV is drawn to a technical feature of a method of modulating the phosphorylation of a human EGFR in cells/tissues.

Therefore, Groups II-XV have different special technical features than Group I and define separate contributions to the art. Accordingly, Groups I-XV are not linked by the same or a corresponding special technical feature within meaning of PCT Rule 13.1 so as to form a single general inventive concept.

3. Furthermore, in addition to the election of one of the above IV groups, further restriction is required under PCT Rule 13.1 to delineate the molecular embodiment to which the claims will be restricted in accordance with the elected group:

A. If any one group from Groups I-XV above is elected, Applicant is required to elect a single designated molecule selected from SEQ ID NOs:1-3. In addition, Applicant needs to indicate the corresponding protein sequence.

4. The restriction is deemed to be proper because the products indicated as group A does not constitute a common special corresponding technical feature. Each polynucleotide/polypeptide differs with respect to its composition, structural feature,

function and use. Since the compositions and amino acid sequences are different, the use, effects and outcomes of each SEQ ID are very divergent. Thus, Groups I-XV have different special technical features since they define separate contributions to the art. Accordingly, Groups I-XV are not linked by the same or a corresponding special technical feature within meaning of PCT Rule 13.1 so as to form a single general inventive concept.

Species Election

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

i. If Group VI is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for a transgenic animal selected from A) a transgene or B) an insertion disrupting expression of an Amigo as recited in claim 19 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 18 is generic.

ii. If Group IX is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for AMIGO selected from A) AMIGO1, B) AMIGO2 or C) AMIGO 3 as recited in claim 29 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic.

iii. If Group XIII or Group XIV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for agent selected from A) AMIGO receptor protein, B) AMIGO receptor DNA, C) AMIGO protein, D) AMIGO DNA, E) antibody/Fab against AMIGO, F) antibody/Fab against AMIGO receptor, G) antibody/Fab that inhibits the polypeptide binding to AMIGO receptor/EGFR as recited in claims 38, 48 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 38 and 48 are generic.

iv. If Group XIII or XIV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for neuronal cells selected from A) hippocampal cells, B) cerebral cells, C) cerebellar cells, D) neuronal trauma cells, E) glial scar cells, F) spinal cord cells, G) optic nerve cells/retina cells, or G) kidney cells as recited in claims 47 and 57 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 38 and 48 are generic.

v. If Group XIII or XIV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for cancer selected from A) glioma, B) germ cell tumors of germinoma cells, C) lung carcinoma, D) breast carcinoma, E) ovarian carcinoma, F) colorectal carcinoma, G) bladder carcinoma, H) pancreatic

carcinoma, I) squamous cell carcinoma, or J) renal carcinoma as recited in claims 50 and 56 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. In addition, If glioma is elected, Applicant is required to further elect a species of glioma selected from a) glioblastoma, b) astrocytoma/anaplastic astrocytoma, c) ependymomas, d) oligodendrogliomas, e) medulloblastomas, f) meningiomas, h) schwannomas, or i) craniopharyngiomas. Currently, claims 38 and 48 are generic.

vi. If Group XV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for AMIGO compound selected from A) AMIGO peptide or B) anti-AMIGO antibody as recited in claims 60 and 61 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 59 is generic.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:
The technical features of these species are different because they different types of molecules, cell types, and diseases. Each specific species of molecules differs with respect to its composition, structural feature, function and use. function. For different neuronal cells, the cell contents and biological characteristics in different neuronal cell types derived from different regions are very different and function differently because

they encompass different neuronal populations. The cell components and biological characteristics are very different in different cell types. Consequently the responses of these different cell types to different biomoleucles are also diverse. Further, the molecular mechanisms underlying the action of each molecule are very different and so are the effects. Moreover, for the disease, the etiology and potential molecular mechanisms contributed to these pathological conditions are different. The pathology and etiologies of neurological injury are very different. The patient populations in each pathological condition are also very different. The health status, the medication, the diagnosis, and the physiological condition in patients are different. It requires different diagnoses, equipments, steps and treatments for these different groups of patients. Thus, these species have different special technical features since they define separate contributions to the art. Accordingly, these species are not linked by the same or a corresponding special technical feature within meaning of PCT Rule 13.1 so as to form a single general inventive concept.

7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-XV and a single designated molecule from group A and a single species from groups i-vi as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

13. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
August 30, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER